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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/627,352 | 07/25/2003 | Vladimir Knezevic | 6457-65777 | 2321 |

7590 02/28/2005

KLARQUIST SPARKMAN, LLP
One World Trade Center
Suite 1600
121 S.W. Salmon Street
Portland, OR 97204

EXAMINER

PADMANABHAN, KARTIC

| | |
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| ART UNIT | PAPER NUMBER |
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1641

DATE MAILED: 02/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------------|--|--|
| Office Action Summary | Application No. 10/627,352 | Applicant(s) KNEZEVIC ET AL. | |
| | Examiner Kartic Padmanabhan | Art Unit 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/21/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-26,28,32-38 and 44-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-26,28,32-38 and 44-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 22-26, 28, 32-38, and 44-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 22, 44, and 46 are rejected as vague and indefinite for the recitation of "adapted" because it is not clear as to how the membrane is configured to perform its intended function of being brought into contact with sample.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sneath (US Pat. 5,264,344) in view of Foster et al. (US Pat. 4,444,879).

Sneath teaches methods for culturing cells on a membrane, wherein the membrane may comprise a plastic film such as polyethylene. The membrane may also have a backing layer. A stack of such membranes may be used to produce multiple copies of cultures of cells. Cells may be grown in the apertures of the membrane which define areas of growth medium (Col. 2). When an aperture is confluent with cell growth, the stack of membranes may be dismantled and the membranes used to inoculate further supplies of growth medium. The reference also teaches the detection of cell products using labeled antibodies or antigens (Col. 3). However, the reference does not teach containers of antibodies.

Foster et al. teach an immunoassay kit comprising containers of various immunoglobulins and enzyme-labeled anti-IgG conjugate (Col. 15 and Figure 6).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the kit comprising containers of probes of Foster et al. with the method of Sneath because the packaging of the necessary components to perform an assay into a kit provides increased convenience and efficiency. In addition, Sneath teaches the use of antibodies,

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which need to be stored in a container at some point prior to use, for which the containers of Foster could have been used.

8. Claims 23-24 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sneath (US Pat. 5,264,344) in view of Foster et al. (US Pat. 4,444,879) as applied to claims 22, 23, and 25 above, and further in view of Chandler (US Pat. 5,877,028).

Sneath and Foster et al. teach a modified kit, as previously discussed. However, the references do not teach nitrocellulose.

Chandler et al. teach an immunoassay device, wherein a nitrocellulose membrane is used, such that antibody could be applied to the membrane for the determination of analyte presence.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the nitrocellulose membrane of Chandler et al. with the modified kit of Sneath and Foster et al. because nitrocellulose is a very commonly used membrane in the art for various assay purposes and provides a suitable material for adsorption of biomolecules. In addition, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

9. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sneath (US Pat. 5,264,344) in view of Foster et al. (US Pat. 4,444,879) as applied to claims 22, 23, and 25 above, and further in view of Pipas et al. (US Pat. 6,168,929 B1).

Sneath and Foster et al. teach a modified kit, as previously discussed. However, the references do not teach the use of an antibody cocktail.

Pipas et al. teach the use of an antibody cocktail to probe analytes blotted onto membranes.

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It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the antibody cocktail of Pipas et al. with the modified kit of Sneath and Foster et al. because one could have used any antibody with the kits of the reference, depending on the analyte(s) of interest, with a reasonable expectation of success. In addition, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

10. Claims 28, 32, 33, 37, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sneath (US Pat. 5,264,344) in view of Foster et al. (US Pat. 4,444,879) as applied to claims 22, 23, and 25 above, and further in view of Mussi (US Pat. 5,665,596).

Sneath and Foster et al. teach a modified kit, as previously discussed. However, the references do not teach a membrane thickness of between 4 and 30 microns or the use of polycarbonate.

Mussi teaches a device for culturing cells, wherein a membrane may be used, wherein the membrane may be formed of polycarbonate. The membrane also preferably has a thickness of between 20 and 30 microns.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the polycarbonate substrate with a thickness of 20-30 microns of Mussi with the modified kit of Sneath and Foster et al. because Mussi teaches the utility of such a substrate in cell culture assays. In addition, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. In addition, although the references do not specifically teach 50 membranes, one of skill in the art would have been able to use any number

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of membranes with the kit of Sneath, Foster et al., and Mussi with a reasonable expectation of success, as it merely represents an optimization of the assay protocol, and it has been held that the mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

11. Claims 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sneath (US Pat. 5,264,344) in view of Foster et al. (US Pat. 4,444,879) as applied to claims 22, 23, and 25 above, and further in view of Chandler et al. (US Pat. Pat. 5,877,028) and Mussi (US Pat. 5,665,596).

Sneath and Foster et al. teach a modified kit, as previously discussed. However, the references do not teach nitrocellulose, a membrane thickness of between 4 and 30 microns or the use of polycarbonate.

Chandler et al. teach an immunoassay device, wherein a nitrocellulose membrane is used, such that antibody could be applied to the membrane for the determination of analyte presence. However, the reference does not teach polycarbonate or membrane thickness.

Mussi teaches a device for culturing cells, wherein a membrane may be used, wherein the membrane may be formed of polycarbonate. The membrane also preferably has a thickness of between 20 and 30 microns.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the nitrocellulose membrane of Chandler et al. with the modified kit of Sneath and Foster et al. because nitrocellulose is a very commonly used membrane in the art for various assay purposes and provides a suitable material for adsorption of biomolecules. It would also have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the polycarbonate substrate with a thickness of 20-30 microns of Mussi with the kit

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because Mussi teaches the utility of such a substrate in cell culture assays. In addition, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Further, although the references do not specifically teach 50 membranes, one of skill in the art would have been able to use any number of membranes with the kit with a reasonable expectation of success, as it merely represents an optimization of the assay protocol, and it has been held that the mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Response to Arguments

12. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Claims 22-26, 28, 32-38, and 44-46 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 571-272-0825. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kartic Padmanabhan
Patent Examiner
Art Unit 1641



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641

2/22/05